CON Task Force Issue Brief

Ambulatory Surgery Services

Statement of the Issue

Should the CON oversight of the development of new ambulatory surgery services be eliminated or modified?

What changes, if any, should be made to the definitions of operating room and procedure room, or any other definition that affects decisions on the Certificate of Need coverage of proposed new freestanding ambulatory surgical capacity?

Summary of Public Comments

The Task Force received comments from three organizations and one individual regarding coverage of freestanding ambulatory surgical facilities by Certificate of Need. All three comments focused on the definitions that determine whether or not proposed new ambulatory surgical capacity in freestanding settings requires Certificate of Need review and approval by the Commission.

Warren A. Green, President and Chief Executive Officer of **LifeBridge Health**, stated his organization's continued support for requiring Certificate of Need approval to establish a new, multi-room ambulatory surgical center. LifeBridge bases its support for continuing to require freestanding ambulatory surgical facilities with two or more operating rooms to obtain a Certificate of Need from the Commission on the fact that such centers frequently place inequitable burdens on hospitals, by "skimming" off well-compensated procedures and well-insured patients. While he notes that hospitals have, with support from the Health Services Cost Review Commission, "accommodated the ASC phenomenon to date," the creation of additional freestanding ambulatory surgical facilities would put the existing equilibrium in jeopardy. Mr. Green encouraged the Commission to consider whether the existing statutory exemption for one operating room facilities "has led to an undesirable proliferation of these smaller centers, and should be reconsidered.

William G. "Bill" Robertson, President and CEO of **Adventist HealthCare**, also urged the Commission to re-examine the "current exemption from CON for physician-owned, single specialty operating rooms." He stated that these services may be duplicative of existing capacity at hospitals, and they compete with hospitals for staffing. Mr. Robertson urged that the Commission more carefully review the impact of these single operating room centers.

The **Maryland Ambulatory Surgical Association** ("MASA") expressed its support for the continued regulation of the ambulatory surgical industry, as a means both of promoting greater freedom of choice of surgical providers, and also of providing a level of oversight that promotes consumer safety

and protection. MASA is strongly opposed to eliminating the CON requirement for ambulatory surgical facilities and services. At the same time, MASA opposes expanding CON regulation, or making "slight modifications which may have unintended consequences," preferring the continuity of maintaining the current framework under which the Commission issues determinations of Certificate of Need coverage.

MASA's membership also supports the development of a consensus among MHCC, the Office of Health Care Quality, and the ambulatory surgical industry on definitions of "operating room" and "procedure room" to be employed in both CON regulation and licensure. There is no definition of "procedure room" currently in the Certificate of Need regulations, and no specificity in current regulations with regard to either kind of room, with regard to their authorized use, by procedure or type of equipment. MASA's concern is that, without more specific guidelines to distinguish these two types of settings, quality of care may be at risk, and an uneven playing field may be created.

Scott E. Andochick, M.D., a board-certified plastic surgeon from Frederick, Maryland, commented on his experience as an individual ambulatory surgery provider trying to compete with hospitals and other larger centers, and the impact of Certificate of Need regulation of ambulatory surgery services. Dr. Andochick cited the opposition of his local hospital to a Certificate of Need application he had submitted, to establish two operating rooms, which ultimately led him to scale back to request and receive a determination of non-coverage by CON for one operating room and two procedure rooms. His comments focused on what he perceives to be the unfairness and "political" nature of the participation of powerful interested parties, in influencing the Certificate of Need process, and preventing well-qualified competitors from entering the market

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Background

Maryland's health planning statute requires a Certificate of Need to "build, develop, or establish a health care facility," and, in its definitional section, includes an "ambulatory surgical facility" among those it defines a health care facilities, for purposes of Certificate of Need coverage. The statute at §19-114(b) defines an ambulatory surgical facility, for the Commission's purposes,[1] as "any center, service, office, facility or office of one or more health care practitioners or a group practice" with two or more operating rooms, that "operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization," and that seeks reimbursement from third-party payers as an ambulatory surgical facility.

In addition, the section of health planning statute that enumerates categories of capital expenditures by health care facilities that do not require Certificate of Need approval by the Commission includes the following provision:

[1] Maryland's licensure law defines "freestanding ambulatory surgical facility" differently, for purposes of licensure by the Department of Health and Mental Hygiene, and for the Office of Health Care Quality's function as contractor for Medicare certification in the state. Maryland did not initiate licensing of freestanding ambulatory surgical facilities (approved by the general Assembly in 1995) until 1999. For purposes of licensure, the Maryland Department of Health and Mental Hygiene defines freestanding ambulatory surgical facilities as any non-hospital outpatient surgical providers that seek reimbursement from payers as a freestanding ambulatory surgical facility. This includes entities with a single operating room, which Commission statute does not define as a health care facility for purposes of Certificate of Need coverage. Office-based practitioners "seeking only professional reimbursement for the provision of medical services" are specifically excluded from licensure requirements. Obtaining Medicare certification is a condition of licensure for freestanding ambulatory surgical facilities in Maryland.

> (8) Nothing in this subsection may be construed to permit a hospital to build or expand its ambulatory surgical capacity in any setting owned or controlled by the hospital without obtaining a certificate of need from the Commission if the building or expansion would increase the surgical capacity of the State's health care system.[2]

The requirement that any new ambulatory surgical capacity built or developed by a hospital obtain Certificate of Need approval, enacted in 1995, presumed that hospital-based outpatient surgical capacity would be subject to the rate-setting authority of the Health Services Cost Review Commission, and therefore would charge higher rates than freestanding facilities. A 1996 provision clarified this requirement, specifically permitting hospitals to acquire existing ambulatory surgical capacity without Certificate of Need approval, with appropriate prior notice to the Commission.

The State Health Plan defines ambulatory or outpatient surgery at COMAR 10.24.11.02F as:

> Surgery performed requiring a period of post-operative observation but not requiring overnight hospitalization. This includes procedures involving the actual use of any cutting instrument, less-invasive procedures involving microscopic or endoscopic surgery or the use of laser for the removal or repair of an organ or other tissue. When not performed in an operating room, minor procedures routinely performed in physicians' offices and clinic settings are specifically excluded.

The Plan contemplates that ambulatory surgery may be performed in any of the following settings:

- hospital operating rooms in which both inpatient and outpatient surgery is performed;
- hospital-based discrete ambulatory surgical facilities or centers located either within the main hospital building or in a distinct facility on the hospital campus, in which operating rooms are dedicated exclusively for outpatient surgery;
- facilities established by health maintenance organizations;
- freestanding ambulatory surgical facilities or centers that operate primarily for the purpose of providing surgical services to patients not requiring hospitalization;
- physicians' offices that include surgical suites and may be Medicare certified as freestanding "ambulatory surgical centers" [ASCs]; and
- physicians' offices and clinic settings that do not include surgical suites.

Since 1986 -- when the General Assembly enacted a provision permitting the establishment of "up to four operating rooms" by a physician or group of physicians in specified medical specialties, treating the physician's or group's own patients -- Maryland has used CON regulation in a limited way to control market entry by new ambulatory surgical providers. The 1986 provision meant, in practice, that no group of physicians representing more than one medical specialty could establish even a single operating room without Certificate of Need approval. In 1995, the legislature broadened the categories of setting that could establish ambulatory surgical capacity ("any center, service, office, facility, or office of one or more health care practitioners"), removed specialty as a consideration in establishing new ambulatory surgical capacity, and removed the requirement that centers treat only their own patients, instead making the number of operating rooms – two or more – the defining requirement for Certificate of Need coverage.

[2] §19-120(K0(5)(viii)(8).

In Maryland, all entities providing ambulatory surgery are licensed as "freestanding ambulatory surgical facilities," as part of a broader category – "freestanding ambulatory care facilities" -- placed into licensing statute in 1995. [§19-3B-01 *et seq*] This licensure category applies to all freestanding (i.e., non-hospital) providers of these services, regardless of whether they required Certificate of Need approval under statute in effect at the time the surgical capacity was established.

Freestanding ambulatory surgical facilities in Maryland are not included in the all-payer rate setting system that applies to all charges for hospital services, including charges for hospital-based ambulatory surgery. Freestanding ambulatory surgical facilities therefore have more freedom to engage in market-based pricing strategies for their services, while hospitals providing the same service are not free to compete on price.

Maryland has more Medicare-certified ambulatory surgery centers – a CMS category that includes small physician office-based centers as well as multi-OR health care facilities – on a per capita basis, than any other state, including those that have had no CON regulation of ambulatory surgical facilities since the mid-1980s.[3] The disincentives to establishing new ambulatory surgery services in these states relate to reimbursement, rather than the presence of Certificate of Need regulation. Maryland had 276 licensed freestanding ambulatory surgery providers as of December 2003; only 17 of these facilities were actually established through the CON review process.

Most states have exercised some control over the supply of ambulatory surgical facilities in the past 25 to 30 years. This time frame corresponds with the period during which demand for outpatient surgery has risen significantly and the freestanding ambulatory surgical facility and practitioner office have emerged as important settings for outpatient surgery. The method of control, certificate of need (CON) regulation, varies substantially in scope among states. According to the American Health Planning Association, 27 of the 37 states with CON programs include the regulation of ambulatory surgery centers under their programs.

- ***Number and Distribution of Ambulatory Surgery Providers in Maryland***

Surgical capacity has increased significantly in recent years. The number of ambulatory surgical providers in Maryland has more than doubled since 1994, and has increased over five fold since 1984, with a significant amount of this increase occurring in the freestanding ambulatory surgical facility sector.

Table 1. Trends in Number of Hospital and Non-Hospital Surgical Facilities: Maryland, 1984, 1994, and 2003

Facility Type	1984	1994	2003
Hospitals with Surgical Facilities	54	51	47
Freestanding Ambulatory Surgical Facilities	7	86	276
TOTAL	**61**	**137**	**323**

Source: Maryland Health Care Commission

[3] Medicare's definition of "ambulatory surgery center" also includes physician offices with what the Commission administratively defines as "procedure rooms," in which physicians perform procedures such as endoscopies, defined in Commission regulations as "primarily diagnostic" in nature, but for which Medicare will pay a facility fee in addition to provider charges.

The Appendix contains data describing the availability and utilization of ambulatory surgery services in Maryland.

Summary of Positions in Support of Alternative Regulatory Strategies

	Deregulate from CON Review	Maintain Existing CON Review
Need	● Because one OR facilities do not require Certificate of Need approval, the "playing field" is uneven, in addressing the question of need for new FASFs. ●The existing exclusion of one OR facilities from CON review in effect partially deregulates this sector, so a total deregulation would not have a significant impact. ●Since Maryland has allowed the ambulatory surgery market to develop with limited oversight, eliminating remaining constraints would permit the market to more appropriately allocate resources	● State Health Plan standards applied in Certificate of Need review hold FASFs to standards to minimum volume as a demonstration of need; this promotes quality and cost-effectiveness. ● Impact on hospitals providing outpatient surgical services may be assessed during the Certificate of Need review process, and considered in review and recommended decision. ● Most of the single OR exempted facilities remain as single specialty and provide limited real competition for hospitals and larger multi-specialty FASFs – they operate as personal operating rooms for single practitioners with low surgical volume.
Access	● FASFs tend to serve higher proportions of insured and privately insured patients than hospitals ●FASFs provide more convenient access for patients than general hospitals ●Although State Health Plan standards applied in Certificate of Need review require charity care policy and Medicaid access, compliance with these policies is difficult if not impossible to enforce.	●Competition for limited staff may add unnecessary costs to the system. ● Because the existing program limits larger, multi-specialty FASFs from entering the market, the formation of a two-class outpatient surgery system , with proprietary FASFs dominating the private insurance and Medicare market and hospitals left with Medicaid and uninsured patients, is constrained.
Cost	● Additional FASFs would stimulate competition and could promote cost efficiencies. ● Larger FASFs could achieve economies of scale by providing services to more clients. ●Reasonableness of charges in the freestanding sector is enforced by the market, not by Certificate of Need regulation.	●State Health Plan standards applied in Certificate of Need review require demonstration of "reasonable charges" by proposed new FASFs. ●May promote unnecessary duplication of facilities (even if fewer and larger facilities are developed) ● Large number of facilities produced by existing program already stimulates competition – deregulation would not have a large impact on increasing competitive intensity. ● Hospitals may be forced to duplicate surgical facility capacity already in place within hospitals in order to effectively compete, on the basis of price, with development of larger, multi-specialty FASFs that could occur with deregulation.
Quality	●Quality/outcomes may be negatively affected by the low volumes of surgery performed by many Maryland facilities. ●Providing sufficient quality oversight to the large number of small office-based surgical facilities in the state is already difficult, given resource constraints at OHCQ.	●State Health Plan standards applied in Certificate of Need review require new FASFs to obtain accreditation as well as licensure. ●In order to compete for payer contracts, many non-Certificate of Need approved centers also obtain accreditation; absence of this market-entry requirement could negatively affect quality of care. ●To the extent that the current program keeps more surgical volume in control of hospital organizations, greater levels of regulatory oversight and peer review may occur.

MARYLAND HEALTH CARE COMMISSION

MARYLAND AMBULATORY SURGERY PROVIDERS

Statistical Profile, CY 2003

INVENTORY OF FREESTANDING AMBULATORY SURGERY FACILITIES

Total Freestanding Facilities	276
Single Specialty Facilities	203
Multi-Specialty Facilities	73
Hospital and/or Health System Affiliated	24
Operating Rooms	296
Procedure Rooms	349

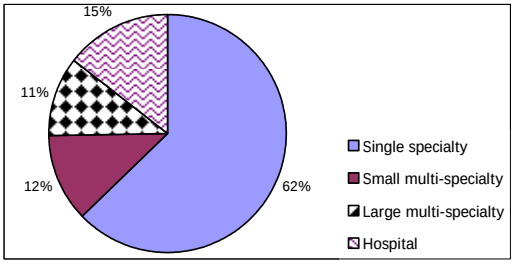
Note: Operating rooms and procedure rooms are defined as sterile and non-sterile rooms, respectively, in which facility fee eligible procedures are performed.

DISTRIBUTION OF FREESTANDING AMBULATORY SURGERY FACILITIES BY JURISDICTION

Allegany County	5	Harford County	10
Anne Arundel County	28	Howard County	9
Baltimore City	20	Montgomery County	60
Baltimore County	64	Prince George's County	26
Calvert County	4	Somerset County	1
Carroll County	10	St. Mary's County	3
Cecil County	2	Talbot County	4
Charles County	3	Washington County	10
Frederick County	12	Wicomico County	5

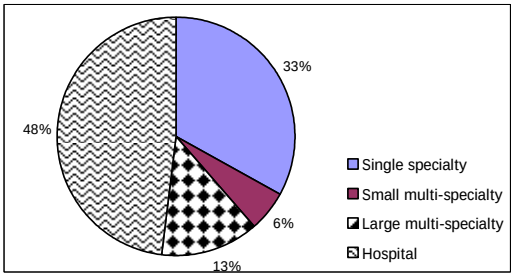
UTILIZATION by Specialty:	2002 Cases	2003 Cases	Difference	Percent Change
Gastroenterology	126,222	147,659	21,437	17%
Ophthalmology	23,702	23,986	284	1%
Pain Management	12,548	17,750	5,202	41%
Plastic Surgery	10,272	11,289	1,017	10%
Podiatry	4,528	5,105	577	13%
Urology	49,220	49,636	416	1%
Other Single specialty	9,038	19,148	10,110	53%
Multi-specialty	161,326	158,512	-2,814	-2%
by Setting:				
Total Freestanding	396,856	433,085	36,229	9%
Hospital Outpatient	396,036	399,692	3,656	1%

AMBULATORY SURGERY PROVIDERS ALL SETTINGS: MARYLAND, 2003



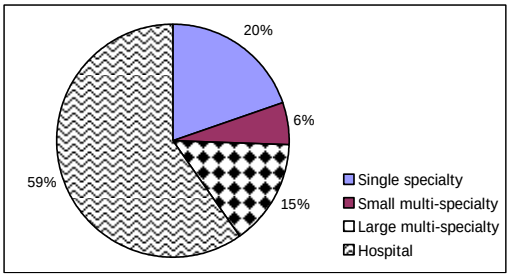
Single specialty = 203
Small multi-specialty = 38
Large multi-specialty = 35
Hospitals with outpatient surgery = 47

AMBULATORY SURGERY CASES, ALL SETTINGS: MARYLAND, 2003



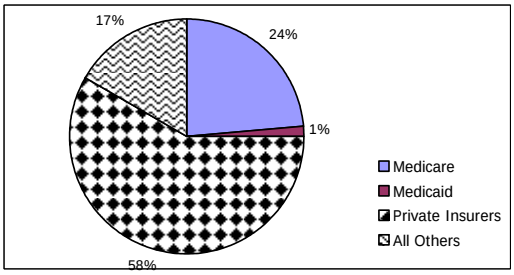
Single specialty = 274,573 cases
Small multi-specialty = 47,493 cases
Large multi-specialty = 111,019 cases
Hospital = 399,692 cases

AMBULATORY SURGERY BILLED CHARGES, ALL SETTINGS: MARYLAND, 2003



Single specialty = $250,653,429
Small multi-specialty = $73,073,641
Large multi-specialty = $186,222,492
Hospitals with outpatient surgery = $758,239,676

FREESTANDING AMBULATORY SURGERY FACILITY NET REVENUE BY PAYER SOURCE: MARYLAND, 2003



Medicare = $63,403,392
Medicaid = $3,886,908
Private Insurers = $157,060,925
All Others (other government, self-pay) = $44,773,249

*Notes: Small multi-specialty refers to facilities that identified 2 or 3 specialties. Net revenue is defined as the difference between total billed charges for surgical services and adjustments for contractual allowances, charity care and bad debt.

Sources: MHCC Freestanding Ambulatory Surgery Survey 2003 and 2002; HSCRC Ambulatory Surgery Database CY 2003.